From: <u>Lynne Bonnett</u>
To: <u>Chase, Cheryl</u>

Subject: Evaluation of RIsk-Based Decision Making
Date: Friday, September 26, 2014 5:58:41 PM

I have only a few short comments.

I think that Health Risk are best evaluated by the Department of Health, not DEEP. Secondly, all brownfields need to be cleaned up; some of the worst are in our urban centers such as New Haven. We do not support a trading system where sites that are contaminated can be exchanged for other sites that are easier to clean up. That, in my opinion, will ensure that the dirtiest and worst sites will remain in our most adversely impacted communities continuing to harm our quality of life.

Thirdly, and not addressed in the plan, is our need to have polluters be responsible for the pollution that they create by adding product costs to cover the costs of dealing with the degradation caused by their pollution.

Thank you for offering the public a chance to comment.

Sincerely,

--

Lynne Bonnett, former chairperson, New Haven Environmental Justice Network 675 Townsend Avenue
New Haven CT 06512.



Ms. Cheryl Chase
Director, Inland Water Resources Division
CT Department of Energy & Environmental Protection
79 Elm Street
Hartford, CT 06106

SUBMITTED VIA EMAIL

(Cheryl.chase@ct.gov)

Dear Ms. Chase,

On behalf of the Connecticut Business & Industry Association (CBIA), thank you for this opportunity to comment on the Aug. 29, 2014 report, "Evaluation of Risk-based Decision Making Connecticut Department of Energy and Environmental Protection" ("the report"), prepared by CDM Smith.

CBIA was a major proponent of Public Act 13-308 including section 28 that requires DEEP to arrange for an independent expert to conduct an evaluation of risk-based decision making related to the remediation of contaminated sites.

CBIA is pleased with the work done by CDM Smith and we support "primary suggestions" 3 through 6 presented as in section 1 of the report and reserve judgment on primary suggestions 1 and 2 pending further discussion. Understanding that the report is "final", we offer the following general comments for DEEP's consideration as it moves forward in this process.

CBIA believes that during the past several years and to its credit, DEEP has begun to understand its role in developing and administering environmental policy as much broader than simply protecting the environment without regard to cost, efficiency and efficacy. As noted in the report, albeit more narrowly in the context of redeveloping brownfields and other contaminated sites, we strongly agree that "successfully addressing [environmental challenges] requires balancing many factors." Connecticut can no longer afford to define its environmental mission as a quixotic quest for a society with zero or near-zero environmental or human health risk based on hypothetical exposure scenarios.

Accepting a reasonable degree of risk is something all of us do every day. According to a 2010 report of the National Safety Council, Americans are exposed to a 1 in 112 chance of dying in a motor vehicle accident, a 1 in 1,043 chance of drowning, a 1 in 83,922 chance of dying in a

<sup>&</sup>lt;sup>1</sup> CDM Smith Report p. 1-1

cataclysmic storm, and a 1 in 136,011 chance of dying from a lightning strike.<sup>2</sup> Yet, Connecticut's standards for cleaning up contaminated property are based on ensuring those who ingest polluted soil for 40 years or consume ½ gallon of polluted water daily for 70 years, expose themselves to no greater risk than 1 in 1,000,000 of acquiring cancer.

The CDM Smith report states that their research indicates "that perhaps the best default criteria are those promulgated by British Columbia<sup>3</sup>. . . where the "no significant risk level is set at  $10^{-5}$  [1 in 100,000] per chemical at any given site." The report further states that "this best risk management approach recognizes that [risk] of up to 1 in 10,000 ( $10^{-4}$ ) are presumptively acceptable – as noted also by U.S. EPA, U.S. Department of Energy, California, Texas, Vermont, and other regions and analysts." We strongly urge DEEP to adjust the baseline risk parameters it uses for determining risk-based criteria consistent with those noted here.

Furthermore, the report also exposes the myth that more stringent standards necessarily equal better environment protection. Specifically, while supporting the notion that best practices require carefully developed default criteria, the report reminds us that "for some properties, strict reliance on [Connecticut] RSR default criteria might well suggest site-actions that are wasteful of resources and not likely to produce actual improvement in public health or ecological health."

With respect to other primary suggestions discussed in the report, we concur with a number of the report's explanations. For example, we agree that "using health risk assessment to address contaminated properties requires both science and judgment." Again, we are pleased that there is a growing recognition among DEEP staff that these complex environmental challenges cannot be successfully addressed through a myopic focus on the most stringent science.

And we strongly agree that whatever methods and attributes are ultimately chosen to define Connecticut's default criteria, they must be "fully specified, reproducible, and dependent on a well-documented set of default assumptions and inputs." This is standard for the best available scientific evidence. It and the other nine attributes of Best management Practices described in Section 6 of the report should be followed without exception.

We also agree with the report that "successful clean-up programs depend on good default criteria, but even the best default criteria cannot be appropriate for all sites" and that there needs to be an expeditious methodology for establishing site-specific, self implementing "non-

<sup>&</sup>lt;sup>2</sup> http://www.nsc.org/news\_resources/injury\_and\_death\_statistics/Documents/2014-Injury-Facts-43.pdf

<sup>&</sup>lt;sup>3</sup> CDM Smith Report p. 1-3

<sup>&</sup>lt;sup>4</sup> Id at p. 1-8

<sup>&</sup>lt;sup>5</sup> Id

<sup>&</sup>lt;sup>6</sup> <u>Id</u> at p. 1-7

<sup>&</sup>lt;sup>7</sup> Id at p. 1-1

<sup>&</sup>lt;sup>8</sup> Id at p. 1-2

<sup>&</sup>lt;sup>9</sup> Id at p. 6-5

<sup>&</sup>lt;sup>10</sup> <u>Id</u> at p. 1-3

standard" solutions. In Connecticut, this process is far from expeditious and is not self-implementing. As a result, especially "advanced-level risk assessment methods [for determining site-specific alternative cleanup criteria] are not often used in practice in the State."

Finally, we particularly note that on the topic of ecological risk assessment, the report states that default risk-based criteria should serve only as "screening levels" as is the case in Massachusetts and many other states and as recommended by EPA.

Thank you very much again for this opportunity to provide comment. We look forward to working with DEEP and other to implement some significant improvements to risk-based assessments in Connecticut that demonstrate the environment and human health can be protected without sacrificing economic gains and efficiency.

Sincerely,

Eric J. Brown

Director, Energy & Environmental Policy

<sup>&</sup>lt;sup>11</sup> CDM Smith Report at p. 1-4





RE: Comments to the Connecticut Department of Energy and Environmental Protection regarding the Final Report titled "Evaluation of Risk-Based Decision Making" prepared by CDM Smith, dated August 29, 2014.

Connecticut Fund for the Environment ("CFE") is a non-profit environmental organization with over 5,500 members statewide. The mission of CFE, and its bi-state program Save the Sound, is to protect and improve the land, air and water of Connecticut and Long Island Sound. We use legal and scientific expertise and bring people together to achieve results that benefit our environment for current and future generations.

Dear Cheryl Chase,

Connecticut Fund for the Environment respectfully submits these comments regarding the Final Report titled "Evaluation of Risk-Based Decision Making" prepared by CDM Smith. We begin with a comment about the methods used in the formulation of report, followed by comments on each of the six recommendations made in the report, and conclude with a comment regarding the overarching issue at hand.

In evaluating risk based decision-making, the paramount concern must, of course, be human health and environmental protection. Within these constraints we must, of course, make the process as quick as is feasible and ensure it results in real cleanups. While there are some good suggestions in the report, we believe that there are also a number of suggestions that deemphasize the need to protect human health and suggest any conclusions taken from the report re-instate this emphasis.

As a matter of opening comment, we note that the evaluators interviewed with staff from DEEP, DPH, EPA and NOAA, to seek information on proposed best management focuses, and past and present conflicts between certain stakeholders and the regulated community. Undoubtedly, the staff at these agencies possess great knowledge and experience with the current system, and certainly can provide the evaluator with valuable insight. We offer the comment that the report could have benefitted from the upfront and continued communication with non-governmental stakeholders, such as environmental, human health, and environmental justice organizations, as well.

CDM Smith - Recommendation 1: "First, we suggest that Connecticut consider amending relevant law to place these four activities — HHRA, HHRM, ERA, and ERM — all within DEEP."

The report recommends moving the human health risk assessment ("HHRA") to within DEEP. We strongly disagree with this recommendation. While we understand it is attempting to streamline the functions into one agency, human health must remain an integral part of this analysis and staff from the DPH has the appropriate expertise, mission, and oversight to do this job. Removing this critical agency from the process would send the wrong message about priorities. Therefore, we recommend that the first recommendation of the report be rejected.

CDM Smith - Recommendation 2: "Second, we suggest that DEEP establish a process whereby property owners, local governmental officials, and other stakeholders are encouraged to develop and present to DEEP, for its approval, nonstandard solutions to improve public health in communities burdened with brownfields. Such solutions could also include improvements to already protected habitats and conservation areas elsewhere in the State, in lieu of costly but likely less effective restoration at the developed sites per se. To the extent that DEEP needs to be granted additional authority to approve such nonstandard solutions (as permanent solutions), the legislature should grant the Agency this authority."

In several places, the report emphasizes the need for site-specific solutions to the problems present at each site. Recommendation 2 calls for the establishment of a process for requesting and approving "nonstandard" solutions to "improve public health in areas burdened with brownfields." It then suggests the possibility of providing for an off-site improvement instead of more costly on-site remediation. This recommendation presents several problems.

While we agree with the desirability of solutions tailored to the needs of each site, we are concerned about the undefined use of the term "nonstandard," and worry about permitting piecemeal solutions on the whim of the LEP or developer. We understand the unique problems that brownfields present, and agree that the current remediation regulatory structure does not adequately provide for their remediation and redevelopment. Instead of creating a system of case-by-case "nonstandard" solutions for the tough-to-solve contamination cases, the entire remediation program should be redeveloped to account for these. The remediation program should incentivize re-development of brownfields and provide special help or tax breaks to reduce to economic burden on owners/developers, but allowing piecemeal solutions to get around the expense of health protective remediation is not the way to do it.

In regard to performing off-site improvements as opposed to more costly on-site improvements, again, this cannot be used as a justification to increase exposures above acceptable risk levels as determined by scientists and professionals. While such projects could serve to offset the damage done to a community from the site, off-site improvements cannot be substituted just because full remediation is more costly.

CDM Smith - Recommendation 3: "Third, we suggest that (i) DEEP fully and electronically document all of the underlying assumptions, models, exceptions, and other aspects of each default criterion in the RSRs; (ii) DEEP consider updating these criteria, per British Columbia's criteria, to account for risks to soil invertebrates and to plants as well as for risks to public health; and (iii) to the extent that legislative involvement is currently required before criteria are updated, this requirement be modified to grant DEEP the requisite authority."

We agree that the health criteria must be updated to reflect modern knowledge about health risks, and that ecological criteria must be included. Our environment, health, and well-being are inextricably connected and we cannot sacrifice one for the other. This must be set, however, at a level that DPH determines is protective of the public health. Political judgments and pressures should not be allowed to play a roll. While stakeholder input is important, it is the regulators, using the best science, which must be determining what is necessary to protect the public health, not the industries.

CDM Smith – Recommendation 4: "Fourth, we suggest that DEEP adopt and, as needed, adapt the successful ecological risk assessment and ecological risk management programs already in place in Massachusetts and in British Columbia."

The report contains minimal reasoning for its endorsement of Massachusetts's and British Columbia's ecological risk assessment and ecological risk management programs. We therefore cannot agree with such endorsement. We advise a more thorough explanation for these endorsements be made which clearly state how the adoption of such practices will help Connecticut's remediation policy protect human health and the environment.

CDM Smith – Recommendation 5: "Fifth, we suggest that DEEP encourage the use of advanced, site-specific risk assessments for sites where application of RSR default criteria may be inappropriate."

This recommendation is another instance of the report's emphasis on site-specific assessment and remediation criteria. We are concerned that the phrase "use of advanced, site-specific risk assessment" which diverts from the default criteria just means: "remediation to a lesser standard." To prevent this, we believe we need strong standards for when deviations can be made, as well as strong oversight and regulation of Licensed Environmental Professionals. Until we get a more vigorous system of oversight, it will be impossible to control the great amounts of discretion given to LEPs and developers on a site by site basis, while still protecting public health. Thus, no deviations should be considered unless it can be documented and assured that the deviation will not meaningfully increase the risk to human health and the environment. Unfortunately, at this point it does not appear that there are resources or a regulatory oversight structure at the agency that would allow this.

CDM Smith – Recommendation 6: "Finally, sixth, for potentially carcinogenic site contaminants, we suggest that DEEP adopt risk management goals for the reasonably maximally exposed individual (RMEI) of up to 1 in 100,000 per chemical, and up to 1 in 10,000 per site."

We strongly oppose this recommendation. This would make Connecticut the only mid-Atlantic state with such a high allowable risk, and this would unfairly and unjustifiably increase the lifetime exposure risks of poorer demographics, who tend to live in closer proximity to contaminated sites. Connecticut should not be blazing a trail toward having the most allowable carcinogens. It is bad policy, and it is dangerous. Therefore we wholeheartedly call for the rejection of recommendation 6 of the report.

In conclusion, we offer one more comment regarding the remediation policy in Connecticut. Over the past several years, there has been tremendous pressure on the legislature and DEEP to steer the regulatory system controlling remediation of contaminated sites toward one which is less protective of human health and the environment, to one that is more economically productive. We caution against losing sight of the most important consideration: the protection of human health. It is pertinent that this consideration be positioned on a greater pedestal than economic interests, because there is no greater need to be protected than human life. Only when the public health is protected and such is documented by DPH, should we start considering the most cost effective ways to move forward.

Instead of doing piece-by-piece reconstruction of the remediation program, which can lead to a disjointed and less protective system, the laws controlling contaminated site remediation should be re-written in a major way and designed intelligently to balance the need to keep remediation economically viable, but still deliver on the primary goal: the protection of human health and the environment.

Sincerely,

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September 30, 2014

Reference No. 400001

Ms. Cheryl Chase, Director
Inland Water Resources Division
Bureau of Water Protection and Land Reuse
Connecticut Department of Energy and Environmental Protection
79 Elm Street, Hartford, CT 06106-5127

Dear Ms. Chase:

Re: Comments on the Final Report – "Evaluation of Risk-Based Decision Making Connecticut Department of Energy and Environmental Protection (CT DEEP)"

Conestoga-Rovers and Associates inc. (CRA) respectfully submits the following comments regarding the "Evaluation of Risk-Based Decision Making – Connecticut Department of Energy and Environmental Protection (CT DEEP)" report (the "Report"), prepared by CDM-Smith and Charter Oak Environmental Services, Inc., dated August 29, 2014. CRA's Risk Assessment Group has reviewed the Report and commends CT DEEP's initiative in developing regulatory guidelines regarding the conduct of human health and ecological risk assessments for contaminated sites in Connecticut.

The risk assessment regulatory process that has been used for several decades is not well understood by involved stakeholders and generally results in overly conservative and cost-ineffective remedial programs to obtain closure and re-use of contaminated sites. Despite lessons learned and recent scientific developments, very little, if anything, has changed in the risk assessment methodology. The development of new guidelines by CT DEEP provides a great opportunity for a paradigm shift toward more meaningful, efficient, and scientifically valid risk assessments.

The recommendations presented in the Report are a good start, especially with respect to conducting Human Health Risk Assessments (HHRAs). This section includes discussion and advice against hyper-conservative approaches such as the discussion regarding target cancer risk levels versus potentially affected populations presented on Pages 6-23 to 6-24 of the Report. It recognizes a critical fact - most all risk assessments for contaminated sites deal with small areas and small numbers of exposed people. Given the small number of people typically exposed, we agree with the Report's recommendation that  $10^{-6}$  target cancer risk level is usually too conservative.

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However, this discussion might benefit from some additional text/clarification. A rationale should be given for the proposed double-criterion scale: a 10<sup>-5</sup> target risk level for individual chemicals and a 10<sup>-4</sup> target risk for all chemicals. Since risks at many contaminated sites are dominated by one or two primary chemicals of concern, the current advice effectively amounts to a target risk for all chemicals of about 10<sup>-5</sup>. Secondly, it can be inferred from the previous discussion that these proposed criteria would be low default values. That is, less conservative risks could be used for very small populations whereas more conservative risk levels (less than 10<sup>-5</sup>) would be discouraged. This default status should be made explicit. Thirdly, it can also be inferred that these target risk levels are to be applied to the Reasonable Maximal Exposure (RME) individual. Again, this probable intent should be made explicit. Fourthly, we recommend mandating the use of the central tendency exposure (CTE) individual, which is usually ignored (as discussed in the Report). Due to the combination of small populations exposed and hyper-conservative exposure assumptions, the RME population size is often most likely to be zero (i.e., no people fulfill all assumptions). RME scenarios for fish consumption and contaminated sediments, in our experience, tend to be especially unreasonable. To make risk assessments more realistic, understandable, and cost-effective, we suggest that default CTE risks be set at about ½ to ¼ those for RME. Mandating use of CTE in risk assessment decisions would constrain exposure scenarios, and risk assessment decisions, to those that may actually occur with some frequency.

CRA welcomes the discussion in the Report regarding the hyper-conservatism of the published risk potency factors. Our concern is that the very high level of conservatism inherent in cancer slope factors, reference doses (RfDs), and exposure scenarios remain unclear to non-expert readers. That is, the current discussion in the Report does not go far enough in explaining just how conservative typical "risk assessments" truly are. The name itself is misleading since "risk assessment" also applies to much more realistic, technically based actuarial risk assessments (e.g., car safety, heart disease), while those for chemical risks include a myriad of overt and hidden safety factors, as wells as embedded policy decisions. For example, the typical cancer slope factor includes use of an upper confidence limit on the worst case bioassay data, and assumes that moderately high dose effects can be extrapolated to very, very low doses. Many scientists, including CRA's Risk Assessment Group, believe that many regulated carcinogens are not, in fact, carcinogens at all at environmental exposure levels. Similarly, RME for some endpoints (e.g., fish consumption) are not, in fact, anything close to "reasonable." It would be good public policy to mandate that risk assessments include some level of cumulative error analysis, in which all the hidden safety factors inherent in a risk estimate are specifically



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addressed and estimated quantitatively. We recognize that this may be technically difficult. However, the uncritical, common-place usage of these ultra-conservative "risk assessment" methods confuses most stakeholders, even experts and regulators, into believing they are realistic assessments of risk. Another option could be utilizing Monte-Carlo risk assessments as default alternatives to the typical deterministic HHRA methods, since good probabilistic risk analyses identify and quantify the total safety factors.

The discussion of ecological risk assessment (ERA) in the Report includes some good elements; however, the implicit recommendation to have *de minimis* areas necessary to trigger an ERA is underemphasized. If ERAs are to be incorporated into the CT DEEP regulatory program, CRA strongly recommends that specific *de minimis* areas should be adopted.

Also, the Report refers to *de minimis* areas of undeveloped land, but a discussion of developed land is notably absent. The value of not considering developed land in ERAs would be to avoid spending money cleaning up what will be, after clean-up, marginal ecological habitat. This is a basic good common sense approach that is rarely considered in the ERA process. Furthermore, another option that should be considered is the opportunity to preserve some equivalent area of good habitat in lieu of costly clean-up of the marginal ecological habitat often found at contaminated sites. Making land acquisition and preservation a default alternative to clean-up would presumably provide more net ecological benefits per dollar spent, and also serve as a *de facto* cost-benefit analysis to constrain ERA-driven risk management decisions.

Fundamentally, CRA believes that the continued use of current methods of ERA is not consistent with good science, expensive, and often counter-productive. First, ecological risk pertains to populations and communities of animals; where losses of a small number of individuals of any population or small areas of habitat are ecologically insignificant. The underlying assumption of current ERA methods, as currently practiced across North America, is that very small areas of usually moderately low contaminant levels can cause ecological risk. This underlying assumption is contrary to the science of ecology. It may not be good public policy to protect most exposed and sensitive species (i.e., the shrews and/or mink) on small areas of usually not very good habitat. However, it seems wrong to continue the misconception that many contaminated sites, in fact, pose real ecological risk.

That ERAs, as currently practiced, almost never address real ecological risk has several implications. First, it is important to recognize that the ERA process diverts public and private resources, and public attention away from real environmental impacts: exotic species



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protection, habitat destruction, and climate change. Remediation of contaminated sites is an inherently ineffective, expensive, and probably illusory method to protect ecological habitat and species of concern. Second, there is reduced rationale for conservatism since most all contaminated sites and areas of impact are too small to cause ecologically significant impacts. Similar to cancer risk evaluations alluded to in the Report; almost all contaminated sites are too small to require the currently used default of very conservative methods for ERAs. To be balanced, CRA recognizes that some sites may, in fact, cause societally-significant ecological effects. However, these are atypical sites that contain all of the following: 1) high concentrations of persistent chemicals; 2) dispersed over large areas; and 3) important biological habitats. CRA recommends that less conservative methods be the default for all contaminated sites except for those very large sites that contain societally-important ecological resources.

A second problem with continuing the current ERA methods is that they are expensive, inefficient, and, AT BEST, capricious and arbitrary. Consider the current state-of-the-practice for Screening Assessments, where the maximum observed concentration is compared to Ecological Screening Values (ESV) that are often too low to be either believable or useful. The net effect of this compounded conservatism is screening assessments that do not screen. Instead, many nuisance compounds are identified as compounds of potential ecological concern (COPECs) even though they have no potential at all to cause toxicity (especially at the small scales of the average contaminated site). Before more valuable time and resources are wasted addressing these spurious COPECs, CRA recommends that risk assessors rescreen using more reliable estimates of mean concentrations and developing more reliable ESVs.

Thus, CRA strongly recommends that more defensible screening methods be utilized as new default methods. Specifically, screening with 95% upper confidence limits (UCLs) **and** mean concentrations except for very small datasets (e.g., less than 10 samples) or when **un-biased** samples yield 95% UCLs greater than the maxima. This change should be very easy to justify since use of the maximum concentration for screening has so many aberrant qualities in addition to inefficiency. Notably, ecological risk pertains to mean exposure, and the maximum is not really relevant. The maximum concentration is also highly unstable across sampling intensity. Worse, maxima respond contrarily to additional sampling: use of the maximum penalizes more complete sampling since maxima go up with sampling intensity. Use of the maximum concentration is also very wasteful: the remainder of the dataset, collected at great expense, is just wasted. Moreover, the maximum concentration is generally the least believable value in any dataset; it is usually an outlier and often the result of biased sampling



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(i.e., known source areas that provide limited ecological habitat). Consequently, of any value in the dataset, the maximum is often the worst estimator of mean conditions. Use of the maximum for screening was never technically justified.

Another serious problem with current ecological screening assessments is the proliferation and use of trivial, unscientific ESVs. Due to a number of conservative pseudo-scientific methods, many widely used ESVs occur in the range of background concentrations. This renders them suspect as toxicological values — it doesn't make any sense that widely occurring species could face frank toxicity from widely occurring concentrations. Occurrence in the range of background values also renders the ESVs not useful, at best, as screening values (especially when only maximum concentrations are considered). (Note that useless is the best outcome for some of the worst ESVs, such as the EcoSSLs for vanadium and antimony. That is, the best outcome is that screening result will simply be ignored. But screening values are widely misunderstood and used as valid toxicological values, so many of these very low ESVs actually impart negative information about potential risks. In these cases, these ESVs are worse than useless.)

CRA believes that ESVs should be explicitly limited to values that have some potential to be both toxicologically legitimate AND useful in screening assessments. For naturally occurring compounds, a base value of the 90<sup>th</sup> percentile concentrations, as in the Dutch soil and sediment Maximum Permissible Concentrations (MPC) ESV (Crommentuijn et al., 1997), would be defensible toxicologically and also much more useful than many currently-used ESVs. For anthropogenic compounds, ESVs should not be set below typical analytical detection levels or typical clean-up levels. For example, many available screening levels of polychlorinated biphenyl compounds (PCBs) and pesticides are at, and sometimes below, conventional detection levels. Use of these ultra-low ESVs triggers insensible behavior before (use of more expensive, more sensitive analytical methods) and after detection of these chemicals (incidental detection of PCBs and pesticides at low levels triggers extensive and expensive evaluation of these spurious COPECs). What is the value of ESVs that are well below likely risk levels and reasonable clean-up levels?

The Report simultaneously recommends a good science and so-called "effects-based" values. The "effects-based" sediment quality benchmarks (SQB) are not, in any way, consistent with scientific methods (Smith and Jones, 2011). They are not actually even "effects" based (Smith, 2008). These values are most probably the result of constrained random sampling of



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background concentrations. This mechanism explains why TEC/ER-L/TEL/LEL¹ for metals closely resemble median background concentrations (r² for regressions of these lower tier SQBs with median background concentrations are > 98%); they are background concentrations (Smith and Jones, 2005 and 2007). Instead of good science, the co-occurrence values are pseudoscience (i.e., technical analyses that purport to be, or can be confused with, good science) (Smith and Jones, 2011), and because they are so poorly understood, they are best characterized as bad pseudoscience. They are also bad public policy since they typically produce ESVs that are essentially equal to median background concentrations, and because they are widely misused and almost always misunderstood. As an alternative, we suggest using the higher tier co-occurrence numbers (PEC/ER-M/PEL/SEL)². Although these higher tier co-occurrence SQBs are similarly bereft of scientific validity, they are higher than lower tier numbers and much more efficient in terms of screening. Alternatively, the Dutch MPC sediment values are transparent, have some scientific underpinning, and are estimated to be above most background concentrations.

The Report's recommendation to employ British Columbia (BC) soil screening levels is problematic in three respects. First is that this recommendation represents an implicit but important policy decision: that the health of soil biota and plants, hereafter termed "worms and weeds", on private land are appropriate assessment endpoints for ERA. This is a critical policy issue that needs to be explicitly and clearly stated, so that readers can understand that this policy is being recommended. The second problem is that this implicit policy is not a good public policy. The guidance of United States Environmental Protection Agency (EPA) and other States indicates that appropriate endpoints for ecological risk should be societally important species and habitats; the worms and weeds on private lands are not of great societal concern. Thus, for example, landowners are usually free to develop their lands into non-habitat for native plants and soil biota – buildings, parking lots, lawns, and agricultural fields. Similarly, a trip to the local lawn and garden center provides the visitor a wide selection of over the counter products developed to kill worms, weeds, and other biological pests. Lastly, we have concerns about the validity of the BC soil screening numbers and grave concerns about other

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These acronyms pertain to the lower tier concentrations for various co-occurrence SQB: threshold effects concentration (TEC); environmental response-low (ER-L); threshold effects level (TEL); and lowest effects level (LEL).

These acronyms pertain to the higher tier concentrations for various co-occurrence SQB: probable effects concentration (PEC); environmental response-medium (ER-M); probable effects level (PEL); and severe effects level (SEL).



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soil-screening levels based on protecting "worms and weeds", such as EPA's EcoSSLs. The latter ESVs are implicitly recommended for compounds lacking a BC criterion. The toxicological datasets for plants and soil invertebrates tend to be very limited; so many soil screening levels for these endpoints are more policy and default assumptions than science. For example, the vast majority of studies used to develop the EcoSSLs for terrestrial plants are based annual agricultural crops that have been artificially selected for rapid growth and high yield at the expense of the genetic diversity inherent in native species. Again, CRA recommends the Dutch MPC numbers, which have a high background concentration as a minimum screening level.

Again, CRA commends CT DEEP's initiative in developing regulatory guidelines regarding the conduct of human health and ecological risk assessment, and their preliminary attempts to make risk assessment more useful and transparent. CRA encourages the CT DEEP to take advantage of this opportunity to be the catalyst for a risk assessment paradigm shift toward more meaningful, efficient, and scientifically valid risk assessments.

Yours truly,

**CONESTOGA-ROVERS & ASSOCIATES** 

Daniel W. Smith, Ph.D.

David R. Johnson, Ph.D.

Steven M. Harris, M.A.Sc., PE(MI)

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At Axis901 901 Main ST Manchester, CT 06040

Ms. Cheryl Chase Director of Inland Water Resources Division CTDEEP

Thank you for the opportunity to comment on *Evaluation of Risk-Based Decision Making – Final Report prepared for CTDEEP, dated 29<sup>th</sup> August 2014.* I applaud CTDEEP initiating this endeavor, which will significantly enhance Connecticut DEEP's Remediation Transformation package to be delivered to the legislature in October. The authors of the report provided a thorough scientific review and analysis of risk-based decision making in other state, federal and international programs within a short period of time.

Because my expertise is in ecological risk assessment, my comments focus on primarily Section 7 Best Practices in Ecological Risk Assessment and Ecological Risk Management. My comments are structured following the outline of the report's recommendations described in the Executive Summary.

Third, we suggest that (i) DEEP fully and electronically document all of the underlying assumptions, models, exceptions, and other aspects of each default criterion in the RSRs; (ii) DEEP consider updating these criteria, per British Columbia's criteria, to account for risks to soil invertebrates and to plants as well as for risks to public health; and (iii) to the extent that legislative involvement is currently required before criteria are updated, this requirement be modified to grant DEEP the requisite authority.1

Adopting standards based on invertebrates and plants similar to British Columbia is not recommended, since there is always uncertainty associated with the derivation of ecologically-based criteria. Default criteria intended to be protective of terrestrial biota are often defined as chemical concentrations in soil below which toxic effects are not observed. Typically sensitive test organisms are selected for soil toxicity tests used to derive these ecologically-based criteria. Sensitive test organisms may not be representative of similar terrestrial species inhabiting a contaminated site.

An alternative approach is recommended for the derivation of site-specific soil criteria protective of invertebrate and plants indigenous to the habitats identified on the site. This approach would be applied in a screening-level ecological risk assessment (SLERA). The selection process of the ecologically-based soil criteria could be described in an ecological risk assessment guidance document. These criteria are widely used in screening-level ecological risk assessments. In 2003, EPA developed a process to derive a set of risk-based ecological soil screening levels (Eco-SSLs) for many of the soil contaminants frequently of ecological concern for plants and animals at hazardous waste sites and provides guidance for their use. [USEPA, 2003 Guidance for Developing Ecological Soil Screening Levels]

Fourth, we suggest that DEEP adopt and, as needed, adapt the successful ecological riskassessment and ecological risk management programs already in place in Massachusetts and in British Columbia.

I support this recommendation. In 1996, I participated in the Massachusetts DEP Ecological Risk Assessment Working Group where decision trees were developed for both terrestrial and aquatic habitats. Sites that offered minimal habitat value were eliminated early in the site investigation process. In 2001,

the Texas Commission on Environmental Quality also established a workgroup comprised of technical experts from industry, government,

consulting firms, and academia to assist in developing ecological risk guidance. This is an excellent example of ERAG, which was created through a collaborative process. The "Final Report" recommends habitat evaluation checklists that are used in Texas, Ohio (EPA), and Oregon (DEQ): truly negligible sites are screened out with a checklist/site visit (e.g., indicating no habitat, receptors, or complete pathways). A habitat evaluation checklist could be readily incorporated into the CTDEEP's Site Characterization Guidance.

I learned from reading the CDM Smith's report that DEEP has two DRAFT documents under development:

- A DRAFT Ecological Risk Assessment Guidance, Connecticut Department of Energy and Environmental Protection; and
- Connecticut DEEP Screening Level Ecological Risk Assessment Guidance Document, DRAFTDOCUMENT.

The completion of these draft documents would justify convening an external working group consisting of industry, government, consulting firms, and academia to assist in the development of the final documents.

It is recommended that CTDEEP also create an internal multidisciplinary committee to establish "Best Practices" for natural resource or ecological valuation that could be used as a tool for CTDEEP site managers for ecological risk-based decision making.

This also suggested to USEPA. "Local and regional regulatory processes are conditioned by community values and economic objectives as well as by ecological conditions. Therefore, aligning the decision and the supporting risk and economic analyses with "what matters to people" is essential to achieve acceptable risk solutions that can be easily and effectively communicated to the public. To achieve such alignment, EPA should increase its understanding of and capacity to utilize ecosystem valuation methods in conjunction with such decisions" [Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision Making: A Report of the U.S. EPA Science Advisory Board]

"Because ecological risk assessments often fail to identify and prioritize uncertainties that may affect the quality of risk management decisions, uncertainties that profoundly affect the results and outcome of risk assessments should be identified and acknowledged during problem formulation. Furthermore, the use of adaptive management with iterative triggers for action offers promise as a way of dealing with uncertainties in ecological risk assessments"

Fifth, we suggest that DEEP encourage the use of advanced, site-specific risk assessments for sites where application of RSR default criteria may be inappropriate.

As a risk assessor with 20-year plus experience, site-specific risk assessments help mitigate uncertainty associated with default criteria such as RSRs, provide better transparency of the risk analysis process and allows for more scientifically-defensible risk management decisions.

Finally, sixth, for potentially carcinogenic site contaminants, we suggest that DEEP adopt risk management goals for the reasonably maximally exposed individual (RMEI) of up to 1 in 100,000 per chemical, and up to 1 in 10,000 per site.

I agree with the recommendation 1 in 100,000 per chemical, and up to 1 in 10,000 per site. The calculation of site cancer risk includes the use of chemical-specific cancer slope factors.

"Slope factors generally represent an upper bound on the average risk in a population or the risk for a randomly selected individual but not the risk for a highly susceptible individual or group. Some individuals face a higher risk and some face a lower risk. The use of upper bounds is generally considered to be a health-protective approach for covering the risk to susceptible individuals, although the calculation of upper bounds is not based on susceptibility data." [EPA/630/P-03/001FMarch 2005 Guidelines of Cancer Risk Assessment. Risk Assessment Forum]

Because the numbers of individuals who would be reasonably maximally exposed at contaminated site in Connecticut cannot be in the millions or tens of millions, allowable individual risk estimates should not be as stringent as 10-6. Approximately 20 years ago, U.S. EPA considered the development of the 10-5 and 10-4 "acceptable" risk levels, using a number of models that were more realistic, since they more readily addressed the uncertainty associated with the use of Modifying Factors and Uncertainty Factors in the development of chemical toxicity values for Carcinogens and also the average 10%+ error commonly associated with reporting analytical data findings at the time. As an environmental professional and a Connecticut resident, I hope that CTDEEP continues to evaluate risk-based decision making beyond what has been presented in this report for the Remediation Program. Other critical aspects of the Remediation Program such as short term exposure risks (significant environmental hazards) per were not evaluated. However, the report serves as a good launching point, although more needs to be done.

Sincerely,

Bonnie Potocki, MS Ecological Risk Assessor/Wetlands Scientist EcoSolutions LLC. From: Nancy Alderman
To: Chase, Cheryl

Subject: Comments to the CT DEEP on their proposals for Remediation Standard Regulations Revision Concepts Risk-

**Based Decision Making** 

**Date:** Friday, September 26, 2014 3:24:52 PM

# Environment and Human Health, Inc. submits comments on CT DEEP's proposed Remediation Standard Regulations for Evaluation of Risk-Based Decision Making

The CT DEEP puts forth the following proposals and Environment and Human Health, Inc.'s comments on each of the proposals:

- 1. This proposal reassigns the risk assessment to DEEP from the Department of Public Health.
- (1) Environment and Human Health, Inc.'s response to this proposal:

Health risk assessment requires interpretation of both human toxicology and epidemiological information within the structure of a qualified health agency. The CT Department of Health (DOH) has the capacity and knowledge needed to accomplish that. The CT Department of Energy and Environment's (DEEP's) decisions are simply a balance between economics and environmental benefits. The CT DEEP lacks the infrastructure needed to make health based determinations. The CT DOH is the only agency within Connecticut that is capable of reaching these needed health-based decisions. This is not simply an exercise in data manipulation but a task that requires health insights and expertise.

- 2. This proposal establishes a process for stakeholders to develop and present non-standard solutions for brownfield properties.
  - (2) Environment and Human Health, Inc.'s response to this proposal:

Non-standard solutions are simply too vague. Substituting the benefits of cleaning up one site for **not** cleaning up another site - is not acceptable. Each site needs to be assessed for its environmental safety on its own. EHHI does not support doing a lesser clean-up at one site just because you have cleaned up another site.

If a site is not properly cleaned to health based standards - then people should be told when they are placed at a higher risk.

- 3. This proposal documents the basis for default remediation criteria and provides for regular updates to reflect evolving science.
- (3) Environment and Human Health, Inc.'s response to this proposal:

This is actually in the current Remediation Standard Regulation (RSR) guidance document. Persons who are remediating sites are encouraged to - and provided and opportunity to - upgrade the RSR based on current science. The option is there because of the prohibitive cost to CT DOH and the state to continually screen all of the scientific literature and research for information that would support higher or lower RSRs.

This recommendation would shifts the financial responsibility onto the state which can be prohibitive because all RSR values will need to be constantly reassessed.

- 4. This proposal adopts an ecological risk assessment and risk management program.
- (4) Environment and Human Health, Inc.'s response to this proposal:

Tiered approaches, although used in some other states, will require proof that they actually work - as of now we do not have that proof. What is needed is a broad review to determine whether critical habitats have actually been protected on this approach. An ecosystem is not

the same as an individual and therefore demands differing strategies.

5. This proposal encourages use of advanced site-specific risk assessment for sites where default criteria may be inappropriate.

# (5) Environment and Human Health, Inc.'s response to this proposal:

The human health issue of <u>inappropriate default criteria</u> should be resolved under point 3 above. The structure of chart 6.3 on page 6.5 reveals the difficulty in defining the criteria that are inappropriate. See below:

- 1. Scientific accuracy
- 2. Protectiveness of human health and the environment
- 3. Proportionality
- 4. Reproducibility
- 5. Appropriateness
- 6. Flexibility
- 7. Specification
- 8. Transparency
- 9. Incorporation of uncertainty/variability
- 10. Stakeholder involvement

In the document chart above, "protection of human health and the environment" are second to 'scientific accuracy' and 'stakeholders' actually come last. Human health must be the first criteria not the last.

Further responsibility for safety is given to the local health departments which have no experience in risk assessment and rely on the DOH for guidance which they will no longer have.

6. This proposal considers risk management goals for carcinogenic contaminants based on size of affected population and nature of risk to the "reasonably maximally exposed individual" to support standards up to 1 in 100,000 per chemical and up to 1 in 10,000 per site.

# (6) Environment and Human Health, Inc.'s response to this proposal

Changing the criteria to I in 100,000 and 1 in 10,000 instead of 1 in 1,000,000 is unacceptable. This opens the issue of "acceptable risk" which is loaded with questions of fairness.

# In summary Environment and Human Health, Inc.'s responds

This report reflects the frustration of brownfield owners and communities with brownfield sites. Frustrated or not -- human health and safety needs to be front and center. The economic costs and values of health dollars spent at other places are offered as a reason for a new approach --- but these are meaningless from the perspective of people who will be inadvertently subjected to higher health risks.

Positions of other states that have not been evaluated for fairness or efficacy can not be used to justify a change in the levels of attention to health in Connecticut.

Submitted September 26, 2014

bv

David Brown, Sc.D. and Nancy Alderman, MES for Environment and Human Health,

Inc.

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Nancy Alderman, President Environment and Human Health, Inc. 1191 Ridge Road North Haven, CT 06473 (phone) 203-248-6582 (Fax) 203-288-7571 http://www.ehhi.org http://ehhijournal.org



# Environmental Professionals' Organization of Connecticut P.O. Box 176

Amston, Connecticut 06231-0176

Phone: (860) 537-0337, Fax: (860) 603-2075

September 29, 2014

Ms. Cheryl Chase CT DEEP, Director of Inland Water Resources Division Sent via Email to: Cheryl.Chase@ct.gov

RE: EPOC Comments on the "Evaluation of Risk-Based Decision Making - Connecticut Department of Energy and Environmental Protection (DEEP)" Report

Dear Ms. Chase:

The Environmental Professionals' Organization of Connecticut (EPOC) respectfully submits the following comments on the "Evaluation of Risk-Based Decision Making - Connecticut Department of Energy and Environmental Protection (DEEP)" report prepared by CDM-Smith and Charter Oak Environmental Services, Inc. dated August 29, 2014. The comments reflect review and discussion of the report by the Board of Directors and the Executive Director of EPOC. We have also encouraged the members of our organization to review the study and provide comments individually.

First of all, we commend the participants, researchers, and authors of the report on providing a comprehensive and well thought out report on the goals, evaluation methods, and results of this important study. It provides a thorough and transparent treatment of the statement of purpose, data and information gathering, and analysis of the complex issue of risk evaluation in environmental matters. It was a significant effort, particularly given the relatively short time frame, which will undoubtedly have a major impact on the continuing Transformation of Connecticut's Cleanup Program. EPOC has been actively involved with DEEP and other stakeholders in this effort, and we continue to offer our resources and support as we go forward.

For consistency with the outline of the report, we will present our comments on the six major items offered for consideration. Additional general or specific comments on other aspects of the study are presented after that discussion.

## 1. Place Human and Ecological Health Risk Assessment and Risk Management within CT DEEP.

We agree that one of the issues impeding the use of site-specific risk assessment is the need for additional expertise within DEEP in this area. As we understand it, this function is currently performed by the CT Department of Public Health (DPH) on an occasional basis when requested by DEEP to evaluate human and ecological risk and adopt appropriate risk management programs. We agree that performing or evaluating site specific risk assessments by the DPH using standards and regulations originating and implemented at DEEP has the potential for creating communication, consistency and efficiency issues. We recommend authorizing the DEEP to evaluate site specific human and ecological risk assessments, i.e., those done by professionals as self-implementing actions (which is consistent with the overall theme of the Transformation effort), as a critical component of the new program.

2. Involving property owners, local officials, and other stakeholders more in risk management at Brownfields sites and allow for nonstandard solutions for Brownfields to be presented to DEEP

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# for approval, including improvements to existing habitats and conservation areas elsewhere in the state in lieu of a costly, likely less effective cleanup at the developed site.

EPOC agrees that the existence of many blighted properties and Brownfields in our state is a challenging issue and that having additional innovative and unconventional solutions to environmental problems could benefit both risk reduction and redevelopment. Input from the public, local agencies, and others can be helpful in identifying current and future goals for the site, concerns of the public and local officials, potential risks, and workable solutions for the environmental issues and redevelopment at a Brownfields site.

We support the idea of allowing more flexibility with respect to nonstandard solutions in certain cases. This will be beneficial, particularly in situations where a combination of environmental, building, and socioeconomic and market conditions have stymied redevelopment of Brownfields, creating pockets and in some instances larger areas of urban blight. These conditions are not confined to our major towns and cities, as many rural areas also have vestiges of the state's legacy of manufacturing and industrialization. For this reason, we recommend and encourage the DEEP to consider use of non-standard solutions at any site and not limited to Brownfields sites only.

On the matter of a nonstandard solution including making improvements to existing habitats and conservation areas in other parts of the state, we agree with the concept that remediation of certain wetlands and other ecological environments could do more harm than good if destructive remedial techniques are required as discussed in the Ecological Risk Assessment section of the report. Adopting best management practices, issuing meaningful and workable guidance from DEEP and others, and implementing a clearer, self-implementing methodology for ERA as suggested in the CDM Smith report will greatly improve the way these are handled in CT. In those instances where a low value wetland cannot reasonably be restored or due to site setting, restoration would not provide reasonable environmental benefit, we support allowing wetland re-creation or enhancement in other parts of the community or state.

3. Document the derivation of all default criteria in RSRs. Adopt standards for soil invertebrates and plants (similar to British Columbia). Allow DEEP to change RSR criteria without going through a full legislative approval process.

EPOC strongly supports full, transparent documentation of the derivation of RSR criteria, including all exposure and other assumptions, target health risk goals, and other considerations that went into their adoption and for any future standards or revisions. We agree that making this information readily available in the form of spreadsheets and other documents, similar to Massachusetts and other states, would be a desirable way to accomplish this and we support that concept.

With regard to adopting standards based on invertebrates and plants similar to British Columbia, we are concerned that the broad application of criteria based on risks to invertebrates, plants, and other items up the food chain could be problematic if applied and enforced broadly. If an approach similar to British Columbia is to be considered, we recommend that the scientific basis for the ecological standards in those regulations be identified and evaluated before changes to Connecticut's regulations are proposed.

EPOC supports changing the approval process for the RSR criteria for all future revisions to existing standards and adoption of new ones as the need arises, with the caveat that the process for revising or adopting criteria be fully transparent, involve wide stakeholder input and opportunity for comment, and,

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most importantly, be based on the best available science, best management practices, and realistic risk evaluation. As in other states, this will allow risk decision making to be based on the best available information and data at all times. This will avoid making risk management decisions based on outdated information that could result in costly, largely unnecessary cleanups or risk reduction measures.

# 4. Adopt and Adapt a Successful Ecological Risk Assessment and Risk Management Program, similar to Massachusetts and British Columbia.

This is unquestionably a vital part of a successful cleanup program and EPOC strongly supports this recommendation. We believe that a tiered approach as used by EPA, Massachusetts, British Columbia, and others is reflective of best management practices and should be instituted in CT. The Massachusetts model, in particular, appears to be well thought out and developed, including the screening process that allows exemptions for situations that do not represent significant habitats that require extensive cleanup. While the British Columbia ecological standards may also be useful, we recommend that the scientific basis for these standards be independently researched and evaluated on behalf of DEEP before decisions regarding their use in CT are made. EPOC additionally recommends that the MA system and EPA methodology be used as models to develop a workable system in CT.

# 5. DEEP should encourage use of site-specific risk assessment where default RSR criteria are inappropriate.

EPOC agrees with this recommendation as it would provide additional risk management options where appropriate and allow for greater flexibility, effectiveness, and "potentially accuracy" (as noted by CDM Smith) of the state's cleanup program. This should result in a program similar to many other states, such as Massachusetts, as well as the federal government. EPOC recommends considering the adoption of a program similar to the Massachusetts Method 3 Risk Characterization, as noted by CDM Smith.

## 6. Modify Risk Management Goals for Potentially Carcinogenic Contaminants

EPOC agrees with the recommendation to adopt a  $10^{-5}$  cancer risk per chemical and  $10^{-4}$  per site in determining risk management goals. The rationale behind the recommendation appears reasonable and appropriate, i.e., that risk evaluation should consider the size of the affected population, the nature of the risk, and other factors. The fact that EPA and many states and British Columbia use the  $10^{-5}$  and  $10^{-4}$  cancer risk factors lends further credence to its wide use and acceptability.

The comparison of theoretical vs. actual risk is also an important point to consider. A site-specific risk assessment option would essentially be based on the best assessment of actual current and future risk rather than the default remedial criteria or alternatives. That in effect would be an assessment based on actual as opposed to theoretical risk.

Another aspect of the calculation of risk factors and criteria that should be evaluated further is the issue discussed by CDM Smith in Section 3.8 of the report. Differences in the calculation of cumulative risk between Connecticut's methodology and that used and recommended by the EPA and many states should be reviewed. Appropriate changes should be made if necessary to be consistent with current best practices in the field.

EPOC Comments on the "Evaluation of Risk-Based Decision Making - Connecticut Department of Energy and Environmental Protection (DEEP)"
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## **Additional Comments**

One additional comment that we have is that the study did not look at how Connecticut and other states and agencies evaluate the subcategory of significant risks or imminent hazards vs. chronic risk. We understand that this task may not have been specifically included in the awarded contract or required by DEEP or others at any time during the study. However, we believe that it is an important issue that deserves further comment and evaluation.

The impetus for this risk study was, at least in part, the regulatory passage of Public Act 13-308, Sections 31 & 32 that proposed to lower the levels of contamination that would be regulated under Connecticut's Significant Environmental Hazard law (22a-6u). That bill proposed to lower the multiplier used to establish the levels of contaminants that under certain scenarios that would be considered an imminent hazard and require reporting and other actions. Divergent stakeholder opinions lead to considerable discussion and modification of that bill prior to its passage last session, attesting to the importance of the issue.

EPOC recommends that a comparison of the significant/imminent hazard determination methods be made within the framework of making risk-based decisions. This does not necessarily have to be a statistics-heavy scoring analysis as were the other issues/questions that were part of the study. It could be done either by DEEP staff in consultation with others or by CDM Smith if possible under the existing contract. EPOC members who are familiar with other programs, such as Massachusetts, could assist in this effort. In addition, EPOC enjoys a close affiliation with the Licensed Site Professional Association (LSPA), which could also provide DEEP with some insight into this matter.

EPOC offers these comments for thoughtful consideration and towards developing a risk assessment process in the state that will lead to a more effective, accurate, and efficient system that should be a model for others. If you wish to discuss our comments or the report in general, we would be happy to meet with you. Thank you.

Respectfully,

Seth Molofsky, Executive Director

SynMolofoly



Geotechnical

Environmental Water Resources VIA EMAIL: <a href="mailto:cheryl.chase@ct.gov">cheryl.chase@ct.gov</a>

Ecological

Cheryl A. Chase Director Inland Water Resources Division Bureau of Water Protection and Land Reuse 79 Elm Street, Hartford, CT 06106-5127

Re: Comments to the August 29, 2014 CMD Smith Report "Evaluation of Risk-Based Decision Making"

Dear Ms. Chase:

It is understood that CDM Smith was contracted by the Connecticut Department of Energy and Environmental Protection (CTDEEP) to prepare a report in accordance with Section 28 of Public Act 13-308, passed on July 12, 2013, charging CTDEEP, in consultation with the Department of Public Health (DPH), to evaluate the risk-based decision making processes related to the remediation of contaminated sites in Connecticut. The final report, entitled "Evaluation of Risk-Based Decision Making" (the CDM Report) was made available for public review August 29, 2014

Per the CTDEEP's request for public input, GEI Consultants, Inc. submits the following comments and information to support the CTDEEP in preparing recommendations for statutory and regulatory changes to the risk-based decision making process.

#### Comment 1:

First and foremost, GEI commends CTDEEP for working with the CDM Smith project team to create a comprehensive and wide reaching document that evaluates the risk-based decision making process in Connecticut consistent with national and international science and practice. Based on our experience performing site-specific risk characterization under numerous state and international regulations, a collaborative risk characterization process that readily allows for site-specific evaluation will almost always result in contaminated site cleanup that is focused, feasible, and health-protective.

# Comment 2:

GEI supports the first recommendation from the CDM Smith Report, that Connecticut law be amended so that CTDEEP is solely responsible for the oversight and implementation of HHRA, HHRM, ERA, and ERM within the context of the Remediation Standard Regulations (RSRs). Successful risk-based decisions making requires a fully integrated and collaborative effort. The currently split responsibility of DPH and CTDEEP has restricted the practical applicability/feasibility of implementing site-specific risk assessment in Connecticut. The current system is simply inefficient and time consuming.

#### Comment 3:

The second recommendation made by CDM Smith's team includes the statement:

"Such solutions could also include improvements to already protected habitats and conservation areas elsewhere in the State, in lieu of costly but likely less effective restoration at the developed sites per se."

This approach must consider the ecological and societal values and services provided by open space and "green corridors" in urbanized settings. In lieu improvements and restoration may provide higher habitat restoration value in specific circumstances; however other site-specific improvements should be considered. For example, vegetative restoration for the purposes of stormwater treatment as a component of contaminated site remediation and restoration in urbanized conditions may also provide alternative nonstandard solutions. Site specific improvements made in urban communities can go a long way to address environmental justice concerns.

#### Comment 4:

The third major recommendation within the CDM Smith Report includes the statement:

"(ii) DEEP consider updating these criteria, per British Columbia's criteria, to account for risks to soil invertebrates and to plants as well as for risks to public health;"

As GEI noted during the September 10, 2014 public meeting, we recommend that the CTDEEP consider the use of guidance-based ecological screening values, in the context or performing site-specific ecological assessments where ecological resources are identified at a site. Instituting RSR regulatory criteria, proposed to evaluate the potential for adverse effects to ecological receptors, may have the unintended result of conservative remedial decisions based on ecological screening values that cause increased environmental harm (habitat destruction), rather than the intended level of protection.

Ecological screening criteria have been developed as conservative benchmarks for use in early stages of ecological risk assessments, to screen out sites or chemicals for which adverse effects in ecological receptors are not expected. To provide conservative levels of protection, these screening-level guidelines are often based on no observed effects level (NOECs) within an individual organism. These NOEC-based risk thresholds are usually considered too conservative unless threatened or endangered species are present, particularly, because unlike remedial criteria in human health risk assessment which are based on endpoints including cancer and non-cancer risks to individuals, ecological risk assessment endpoints are most often the protection and maintenance of ecological populations. Community-based evaluations should be considered to assess the potential for chemicals of concern to impact and ecological population.

In addition, generic ecological screening criteria also do not take into account the many chemical and physical factors in the natural sediment environment, such as total organic carbon, that tend to reduce the bioavailability and, hence, toxicity of the chemical of concern.

One important example is the evaluation of the potential for adverse effects in a wetland environment. Remedial decisions based on overly conservative ecologically-based criteria may direct remediation in a high quality system. Criteria-based screening does not account for the ecosystem services provided by the high quality wetland habitat, or the limited bioavailability of

contaminants in an organic rich environment, which could be evaluated in a site-specific ecological risk assessment.

#### Comment 5

The fourth recommendation made by CDM Smith's team states:

"Fourth, we suggest that DEEP adopt and, as needed, adapt the successful ecological risk assessment and ecological risk management programs already in place in Massachusetts and in British Columbia."

While GEI agrees with the CDM Smith Report recommendation to adapt ecological risk assessment and ecological risk management programs, we provide some alternative recommendations for developing CTDEEPs programs based on our working knowledge and experience conducting ecological risk assessments at CERCLA site, at sites within various state regulatory programs including Massachusetts, New York, New Jersey, and in Canada.

Section 7 of the CDM Smith Report did not clearly document the current state of practice of Ecological Risk Assessment within the United States. Specifically, the majority of state environmental remediation regulatory agencies refer to the USEPA eight-step process (USEPA 1997) as the primary basis for their Ecological Risk Assessment process and guidance documents. Table 1(Attachment A) provides an overview of many of the state-specific ERA methodologies reviewed in Section 7 of the CDM Smith Report in the context of the USEPA eight-step methodology and which components of the USEPA methodology were addressed. (It should be noted that there were some discrepancies between our review and the CDM Smith sumamary, such as the break out of the Ecological Evaluation and Ecological Risk Assessment components of the NJDEP Ecological Risk Assessment Process, and the terminology applied to the stages of the Texas Ecological Risk Assessment Process.)

GEI recommends that CTDEEP review the Draft Ecological Risk Assessment guidance documents for the states of New Jersey (*Ecological Evaluation Technical Guidance – August 2012*) and Texas (*Conducting Ecological Risk Assessments at Remediation Sites in Texas – January 2014*) in addition the Massachusetts program. The British Columbia methodology is a beneficial reference, but is not based on the current state of the practice of Ecological Risk Assessment within the United States. On the other hand, Massachusetts and New Jersey have established site remediation professional programs similar to regulatory program in Connecticut.

New Jersey and Texas guidance documents were developed more recently than the Massachusetts guidance and ecological updates. New Jersey's Ecological Evaluation guidance therefore incorporates new and developing concepts such as consideration of evaluation and comparisons to the background conditions, assessment of bioavailability for specific chemicals/contaminants considering environmental conditions, and specifically discusses the role of ecological risk assessment in supporting remedial management decisions with a focus on consideration of the ecosystem services of wetlands. CTDEEP should support the development of solution-focused ecological risk assessments.

All three of these State ecological risk assessment programs have developed tiered approaches, as recommended by the CDM Smith Report, and currently proposed by CTDEEP.

#### Comment 6

GEI agrees with the fifth recommendation within the CDM Smith Report, that CTDEEP encourage the use of advanced, site-specific risk assessments for sites where application of RSR default criteria may be inappropriate. However, based on our experience, despite site-specific risk characterization being permitted under the RSRs, the application of site-specific risk assessment in practice has been limited. This sentiment echoed amongst Connecticut Licensed Environmental Professional (LEPs) and the regulated community is that CTDEEP and the Department of Public Health (DPH) are not responsive to site-specific risk characterization. In addition, the use of such approaches requires direct regulatory oversight, which is limiting, in the otherwise LEP decision-based regulatory program. While a regulatory change may help promote more site-specific risk characterization, we feel the issue is more systemic. We encourage CTDEEP and DPH to look within and address the resistance to allowing more site-specific risk characterization. Without first addressing this issue internally, regulatory changes may be ineffective.

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#### Comment 7:

The primary goal is to work with legislature to allow for a framework by which site-specific risk characterization can be conducted in Connecticut. We recommend highlighting that the risk management criteria for Connecticut ( $10^{-6}$  per chemical,  $10^{-5}$  site wide) are consistent with regional, neighboring regulatory agencies (i.e. Massachusetts) where site-specific risk characterization is embraced and effective at facilitating contaminated site closure, as opposed to relying on more distant agencies (i.e. British Columbia, California, Michigan, Texas) to support less stringent risk management criteria. In light of the public and political pressures that must be overcome to reach that goal, it seems that using more tangible, local, and familiar examples of how Connecticut's current risk management criteria can be effective is a more palatable position for all parties. This approach will likely have more influence on the legislature than proposing less stringent criteria based on regulatory agencies that have little to no affiliation or familiarity to Connecticut.

#### Per CDM Smith Report sixth recommendation:

"Finally, sixth, for potentially carcinogenic site contaminants, we suggest that DEEP adopt risk management goals for the reasonably maximally exposed individual (RMEI) of up to 1 in 100,000 per chemical, and up to 1 in 10,000 per site"

We advise caution in proposing less stringent target risk management criteria based on consideration of currently exposed populations. While we acknowledge the concept of varying risk management criteria for maximally exposed individuals (typically less stringent) versus exposed populations (typically more stringent), the CDM Smith Report imparts a tone of overlooking potential foreseeable site uses. For example, relying on current site use to set risk management criteria for an abandoned brownfield where only transient trespassers are present will likely not be protective for all potential future site redevelopment (ie, recreational or residential use). To allow for a less stringent risk management criteria, it is common to place land use restrictions on properties that do not achieve a level of cleanup for some unintended, yet potential future use. We recommend that any proposal to the legislature for setting less stringent risk management criteria based on current site use must also identify how potential future site use will be addressed.

#### Comment 8:

The review approach taken by the CDM Smith team was internally focused, with the majority of interviews conducted with CTDEEP representatives. This approach is beneficial in understanding

the interests and direction CTDEEP has in implementing risk-based decision making approaches within Connecticut, however, it is limits the understanding of how similar regulatory changes have been successfully implemented in other state regulatory programs, which could inform and provide strategies for CTDEEP. As noted above, understanding the approaches taken in similar regional regulatory programs is essential to CTDEEP's success. Consulting with representatives involved with develop risk-based decision making approaches within the Massachusetts LSP program and NJDEP LSRP programs can support CTDEEP's efforts. The approaches taken in other states, if used in conjunction with some of the unique strengths of the CTDEEP program, e.g. the current groundwater classification system, will produce an effective risk-based remediation program in Connecticut.

## Comment 9:

Although the Remediation Standard Regulations Evaluation of Soil and Sediment report to the CTDEEP on The Draft Proposed Program Outline for a Transformed Cleanup Program (Hogan L., Trombly, G. et al. 2012) was mentioned several times in the CDM Smith Report, risk-based evaluation of sediments was not explicitly discussed. The Hogan & Trombly report recommends a tiered risk-based evaluation approach for sediment assessment, with references including the NJDEP methodology.

Sediment assessment lends itself to risk-based decision making. Human exposures to impacted sediments are often limited; therefore, potential for adverse effects to ecological receptors are a primary objective; specifically benthic organisms inhabiting sediments are frequently selected as the assessment endpoint most critical to identification of risk-based clean-up criteria. Risk-based assessment of sediments can provide a significantly higher level of site-specificity, incorporate COPC bioavailability, and greatly reduce uncertainties in the accuracy or level of protection afforded by instituted sediment quality guidelines. Advanced methods of assessment include sediment toxicity testing, analysis of benthic community structure, and weight of evidence approaches combining multiple lines of evidence. These site-specific approaches are almost always less conservative than generic sediment quality guidelines, but provide a much more accurate determination of ecological risk that is specifically linked to the desired levels of protection needed.

#### **Comment 10**

GEI recommends that the implementation of a workgroup to support the development of draft Ecological Risk Assessment guidance documents for Connecticut. The approach should be similar to those work groups developed for the Transformed Cleanup program roundtables. This approach was implemented in both Massachusetts and New Jersey for the development of ERA guidance documents. Not only will this reduce the demands in CTDEEP personnel, but the applied knowledge and perspectives of practicing ecological risk assessors, and LEPs in conjunction with the DEEP regulatory perspective will support the development of a well-rounded state-of-the-practice working guidance document.

GEI is interested and willing to participate in this work group if it is established.

We appreciate the opportunity to provide recommendations to CTDEEP as they move forward in this effort. If you have any questions or would like addition support, please feel free to contact us at 860-368-5300.

Sincerely,

GEI CONSULTANTS, INC.

Kimberly B Bradley

Senior Professional/Ecologist

Musty Back Benty

Enclosures.

Joseph Roman

Project Manager / Senior Scientist

Table 1. Summary of State-level Ecological Risk Assessment Methodologies in the context of the USEPA 8-step Ecological Risk Assessment Process (USEPA 1997).

Federal ERA CERCLA Process		Connecticut	Massachusetts	New York	New Jersey	California	Montana	Texas
Step 1 - SLERA problem formulation & toxicity evaluation	Screening Level Ecological Risk Assessment (SLERA)	Scoping-Level Risk Assessment	Method 3 Environmental Risk Characterization (ERC) Stage I Environmental Risk	Fish and Wildlife Resource Impact Assessment (FWRIA) Requirement	Ecological Evaluation (EE; Formerly BEE)	Scoping Assessment	Level 1/2/3/4 Ecological Risk Analysis (ERA)	Teir I : Exclusion Criteria Checklist
Step 2 - SLERA exposure estimate and risk calculation		Screening Level Risk Assessment	Screening	FWRIA Part 1 - Resource Characterization		Phase I/Phase II Predictive Assessment	Level 3/4 ERA	Teir II: Screening Level Ecological Risk Assessment (SLERA)
Step 3 - BERA problem formulation		Site-specific Ecological	Method 3 ERC	FWRIA	Ecological			
Step 4 - Study design and data quality objective process  Step 5 - Field sampling plan	Baseline Ecological Risk Assessment (BERA)	Risk Assessment	Stage II Environmental Risk	Part 2 - Ecological Impact Assessment	Risk Assessment (ERA)	Phase III Predictive Assessment	Level 4 ERA	Teir III: Site-Specific Ecological Risk
verification Step 6 - Site investigation and data analysis Step 7 - Risk characterization			Characterization			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		Assessment (SSERA)
Step 8 - Risk management	Record of Decision	Remedial Action Plan	Apply to RAO Selection	Ecological Effects of Remedial Alternatives	Remedial Measures	Ecologically-based Remediation/ Ecological Monitoring	Remedial Decision	Ecological Risk Management

# Refernces:

CTDEEP Ecological Risk Assessment Guidance: http://www.ct.gov/deep/cwp/view.asp?a=2715&q=325016&deepNav\_GID=1626

MA DEP (1995). Guidance for Disposal Site Risk Characterization in Support of the Massachusetts Department of Environmental 🛭

Protection Bureau of Waste Site@leanup and Office of Research and Standards. Boston, MA. July 1995. Available at ttp://www.mass.

NYS DEC (1994). Fish and Wildlife Impact Analysis for Inactive Hazardous Waste Sites (FWIA). Dctober 1, 1994. Available at http://www.dec.ny.gov/docs/wildlife\_pdf/fwia.pdf. NJ DEP (2012). Ecological Evaluation Technical Guidance. Version 1.2. August 29, 2012. Available at http://www.nj.gov/dep/srp/guidance/srra/ecological\_evaluation.pdf.

Cal EPA (2013). Preliminary Endangerment Assessment Guidance Manual. State of California Environmental Protection Agency; Department of Toxic Substances Control.

Interim Final - Revised October 2013. Available at http://www.dtsc.ca.gov/SiteCleanup/Brownfields/upload/Preliminary-Endangerment-Assessment-Buidance-Manual.pdf

MT DEQ (2014). State Superfund Process Flowchart. Available at http://www.deq.mt.gov/\stateSuperfund/PDFs/statesuperfundchart.pdf.

TCEQ (2014). Conducting Ecological Risk Assessments at Remediation Sites in Texas. Texas Dommission on Environmental Quality. January 2014. Available at 🛽

http://www.tceq.texas.gov/assets/public/remediation/trrp/rg263-draft.pdf.



TO: Connecticut Department of Energy and Environmental Protection RE: Evaluation of Risk-Based Decision Making" prepared by CDM Smith

COMMENTS FROM: Rivers Alliance of Connecticut

DATE: September 30, 2014

Thank you for sponsoring this report and for the chance to comment.

Rivers Alliance has participated in some of the workshops associated with the proposed transformation of remediation programs. We appreciate the importance of these programs to human and environmental health and to the economy. We are not expert in the science, so will restrict these comments to general principles and a few questions.

This is a sophisticated and valuable report, and we regret not having the resources at the moment to delve into it fully. However, we would be pleased to participate in ongoing study and discussion.

## **COMMENTS**

There are two common reasons for changing remediation standards: 1) research demonstrates that the target contaminant is either more or less harmful than previously known; 2) there is no change in the assessment of the contaminant, but existing clean-up goals are regarded as unsatisfactory because they are impossible to achieve or do not reduce potential harm, or are regarded as too burdensome given other socio-political goals. It is important to be clear about the reason and evidence for recommending and/or implementing a change.

In the introductory section the report states that it:

"... makes suggestions, based on these best practices, for the reform of *health* risk-based contaminated property assessment and management in Connecticut."

[emphasis added]

This will imply to some readers that the risks to be examined are primarily risks to human health; we ask that risks to ecological health be examined and explained more fully. Granted that subsequently the report gives somewhat more weight to ecology, we still worry that it is short-changed. Thus, "Our research has indicated that perhaps the best default criteria are those promulgated by British Columbia, as part of their Contaminated Sites Regulation .... These criteria are appropriately protective of both public health and *some* aspects of ecological health (primarily with regard to soil invertebrates, such as earthworms, and plants)." [emphasis added)

Ecological health gets more attention perhaps in the second-choice sources: "And, as recommended by the soil and sediment workgroup cited above (Hogan, Trombly, et

al., 2012), states such as Massachusetts, New Jersey, Pennsylvania, and Wisconsin have well developed programs that provide ecologically-based guidance for risk-based site assessment and management. "

"[The] most important attributes of **best practices** for site risk assessment and management are **Scientific Accuracy** and **Knowledgeable Stakeholder Involvement**."

Definitions of *best management practices* in the Connecticut scheme of law tend to muddle scientifically optimal practices with "not-too-expensive" practices. Both types of consideration are important but they are not interdependent. "Knowledgeable Stakeholder Involvement" should only mean obtaining expert opinion on what the best existing practices are. Non-expert community stakeholders will, of course, play a role in deciding what is actually done and when.

Estimates of exposure and risk should clarify how exposure is being measured. Is the exposure being averaged out over a year even though it is actually only seasonal or even more limited? There is a kind of mathematics that can transform a lethal dose of arsenic into a therapeutic remedy. It is also should be clear to what extent exposure will be riskier for certain populations: pregnant women, infants, pets, etc. The following paragraph raises red flags.

"Next, with regard to protection of public health and the "reasonably maximally exposed individual" (RMEI) in particular, we note that British Columbia's CSR default criteria for known or suspected carcinogens are established at a human health risk estimate-limit of 1 in 100,000 ( $10\Box 5$ ) per chemical, rather than at 1 in 1,000,000 ( $10\Box 6$ ); and that, based on the judgment of the local public health official, the clean-up criteria can be less (but not more) stringent than the default criteria." [emphasis in the original]

Who is this RMEI? Am I an RMEI? Is the potency of carcinogens really one-tenth of what has been assumed? Which local health official do you have in mind here? Our health districts are not presently up to the task of assessing health threats on contaminated sites. This reference to health officials is contradicted later by the recommendation that risk assessment be transferred entirely to DEEP.

More generally, the criteria and standards for clean-up should be generally available to the public, electronically.

The use of (LEPs) licensed environmental professionals for assessment, planning, and management of contaminated sites has been intensely debated in Connecticut in the last three years. If the person responsible for the contamination or the person owning an interest in the site is the person who chooses, supervises, and pays the LEP, the conflict of interest will overwhelm good intentions.

In the recommendations, the emphasis on non-standard solutions is worrisome. This approach resembles some of the alternative mitigation plans proposed when a project is going to destroy, say, a wetland. The typical (but not inevitable) result is a destroyed wetland and a new, mostly dead pond somewhere. <u>Any use of non-standards solutions</u> should be based on a rigorous enforcement plan and process.

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Flexible, site-specific solutions are only as good as the people framing an d managing the plans. Connecticut has an unsatisfactory record on brownfield clean-up. How will DEEP and others put together teams that are scientifically and politically capable of achieving safe, transparent clean-ups?

Connecticut has made a large investment in protecting its high quality surface water sources. It is important that these assets be given full attention when assessing contamination.

Thank you, Rivers Alliance of Connecticut Margaret Miner, Executive Director rivers@riversalliance.org 860-361-9349



# RISK MANAGEMENT INCORPORATED Health & Environmental Services



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30<sup>th</sup> September 2014 RMI Project 2014-190-00

Ms. Cheryl A. Chase, P.E. CT DEEP 79 Elm Street Hartford, CT 06106-5127 THE PUBLIC COMMENTS PROVIDED BY RMI IN THIS LETTER ARE PRESENTED, AS IS, WITHOUT PREJUDICE. NO WARRANTY, EXPRESS OR IMPLIED IS MADE IN THE USE OF OUR COMMENTS OR AS TO THE ACCURACY OF THE STATEMENTS MADE.

Subject: Public Comments: Connecticut Risk-Based Decision Making – Final Report

Connecticut Department of Energy & Environmental Protection Report Prepared by Charter Oak & CDM Smith, 29<sup>th</sup> August 2014

Dear: Ms. Chase

This letter is in response to your request for Public Comments made at the Public Meeting to present the subject report on the  $10^{th}$  September 2104 at the CT DEEP Phoenix Auditorium, Hartford, Connecticut (CT).

RMI has been very interested in the development of the subject report funded by DECD, since we were the first MA Risk Assessors in CT to conduct and have approved by CTDEP (at the time) Alternative Criteria derived using an EPA/RAGs Risk Assessment for Human Health & the Environment under the direction of Mathew E. Hackman, P.E. CHMM, LEP, LSP for VPH and EPH fractions from a No. 4 Fuel Oil Release.

RMI was also part of a team that bid on this project and had proposed a very similar approach to that taken by Charter Oak & CDM Smith to address CT DEEP's Work Outline for Scope, Task 1 and 2, plus specific areas to be addressed under these Tasks.

Accordingly, we are not surprised by the contents of the Final Report and its Recommendations.

# Namely:

**First** - We totally agree with placement of HHRA, HHRM, ERA and ERM under the CT DEEP umbrella to facilitate coordination of their respective roles and obligations, especially as they relate to the Risk Assessment & Risk Management components of the "CT Chemically Contaminated Sites Cleanup Program."

From RMI's past project experience, the existing structure/responsibilities did not readily facilitate the development of Alternative Pollutant Criteria, the review process and ultimately site closure.

We still have clients with a number of open sites at this time awaiting comments or acceptability even after 2-5 years in the "pipeline." In some cases, comments came back asking us to use "proposed" CT DEEP Revised Guidance Documents, which were never enacted by the Legislature, and have since been withdrawn from CT DEEP's website.

**Second** – This recommendation is laudable with a view to potentially reducing cleanup costs and expediting site closures. However, from RMI's past experience with large and/or private sector stakeholders, in some cases our Risk Assessors have been pressured by these individuals to propose non-standard solutions that we do not truly consider fully protective of Human Health, Public Welfare and the Environment. In those situations, we have declined the Risk Assessment commissions!

**Third** – We totally agree with this recommendation, since we have encountered both mathematical errors and/or inconsistencies in exposure assumptions used in the algorithms to develop alternative criteria published in the RSRs, even those included in the amended June 27, 2013. Section 1. Sections 22a-133k-1 to 22a-133k-3, inclusive, of the Regulations of Connecticut State Agencies. Official corrections to the algorithms used to develop the current Volatilization Criteria for Soil and Groundwater have not been officially acknowledged or published to our knowledge. Although the exposure assumptions for Residential Default Volatilization Criteria were corrected in an Internal Draft Memorandum for revisions to the RSRs and their derivations in a 2008 Internal Memorandum, but not identified as such, and since withdrawn from CT DEEP's website.

In 1996, RMI reported errors to the Department of Environmental Protection, Bureau of Water Management in the algorithms and Correction Factors used to calculate the Residential Default DEC and GWPC and other values. However, this was not acknowledged until November 18, 2002 in a CTDEP Internal Memorandum dated November 18, 2002!

Issues such as those described above would hopefully be readily addressed in the future using the recommended centralized, electronically documented information on assumptions, models, exceptions and other aspects of default criteria. Needless to say, this recommendation should also mitigate time wasted as Risk Assessors in attempting to develop Alternative Criteria (*using current CT DEEP incorrect RSR algorithms*) that cannot be charged to clients.

**Fourth** – We agree with these comments and recommendations and understand that a colleague of ours, Bonnie Potocki from EcoSolutions Inc. is expected to comment on these separately in more detail.

**Fifth** – Again, RMI fully supports this recommendation for the use of site-specific Risk assessments where RSR Default Criteria may be inappropriate. As mentioned earlier, we successfully conducted a site-specific Risk Assessment (*in accordance with EPA/RAGs Risk Assessment Guidance per CT RSRs*) that was equivalent to the MCP Method 3 Risk Characterization for Human Health, Safety, Public and the Environment, in order to develop Alternative Criteria for VPH/EPH fractions detected in a No. 4. Fuel Oil Release. Both the Risk Assessment and derived Alternative Criteria were approved and accepted by CTDEP at the time.

However, we caution against the development and use by CT of the equivalent of a MassDEP Method 3 Shortform Risk Characterization for Human Health, which has been problematic when used by LSPs here in MA and by LSP/LEP's (CT), being nicknamed the "Plug & Chug" approach to Human Health Risk Assessments. Primarily, because of overly conservative default or non-compliant EPA Exposure Assumptions for receptor age-groups, out-of date Toxicity Values for the Chemical Contaminants listed, and incorrect algorithms and Plant Uptake Factors (PUFs) for the Residential "Homegrown Fruits & Vegetables Exposure Scenario; the latter give rise to incorrect Excess Lifetime Cancer Risks (ELCRs) and Non-Cancer Hazard Indices (HIs). Example: MA MCP Lead Soil Standard S-1/GW-1 at 200 mg/Kg yields an HI<sub>c</sub> = 10 and an HI<sub>sc</sub> = 20; MA MCP Arsenic Soil Standard S-1/GW-1 at 20 mg/Kg yields an ELCR = 3 x 10<sup>-4</sup>; HI<sub>c</sub> = 2 and an  $HI_{sc} = 3$ ). To MassDEP's credit, use of the latter exposure scenario is no longer considered acceptable. Instead, MassDEP has been and continues to develop "Best Practices" Guidance for mitigating potential exposures to residual chemical contaminants in site soils, especially in the root zones of fruits, vegetables and other cultivated produce destined for human consumption, primarily in the residential setting, but also for use in public cultivated allotments. etc. However, as a precaution RMI still uses an MCP Method 3 Risk Characterization for Human Health for direct and indirect soil exposures to the chemicals in question via the oral, dermal and inhalation exposure routes in tandem with MassDEP's current Best Current Management Practices.

It should be noted MassDEP now recommends/advises that use of the MA Shortform by LSPs is undertaken using a qualified Risk Assessor. A number of LSPs who haven't heeded MassDEP's advice have received Notices of Non-Compliance (*NONs*) because of failure to also address risk of harm to Safety, Public Welfare & the Environment per the requirements of 310 CMR 40.0990 for an MCP Method 3 Risk Characterization!

Accordingly, RMI would discourage development of such a "Shortform" for Human Health Risk Assessments Exposures as part of an option for site-specific Risk Assessments in CT. Period.

**Sixth** – RMI again agrees with the recommendation of using an Individual Chemical-Specific Cancer Risk Limit of 1 x 10<sup>-5</sup> and a Total Site Cancer Risk of 1 x 10<sup>-4</sup> under certain circumstances, based on the: size of the impacted population; nature of risk (*theoretical or actuarial*) and the size and type of uncertainties. Use of inflexible "bright lines" has always been problematic in Risk Assessments for Hazardous Chemicals and Radionuclides because of the potentially high uncertainty associated with the fixed values under widely varying site conditions.

As noted in the subject Final Report (*Table 6-2, page 6-25*), the respective Risk Limits in CT and MA are  $1 \times 10^{-6}$  and  $1 \times 10^{-5}$  versus EPA's current Total Site Acceptable Cancer Risk Limit Range for the Reasonably Maximally Exposed Individual (*RMEI*) of  $1 \times 10^{-6}$  to  $1 \times 10^{-6}$  to  $1 \times 10^{-6}$  to  $1 \times 10^{-6}$  to an individual – (see 40 CFR § 300.430(e)(2)(I)(A)(1))

In fact, it should also be noted that over the years, acceptable Lifetime Exposure Cancer Risk Limits have changed (e.g., EPA OSWER's RAGs Volume 1, Human Health Evaluation Manual (Part A – 1989 Interim Final), where NCP Site Remediation Goals for Cumulative Cancer Risks ranged from  $1 \times 10^{-4}$  to  $1 \times 10^{-7}$ , in part to address the uncertainty of the derivation of Class A, B1 and B2 Carcinogens' Oral Slope Factors (OSFs) (from Low Dose Linear Extrapolation

Models) to current use of Multistage models (with linear extrapolation from the point of departure (BMDL10), followed by route-to-route extrapolation to the oral route and interspecies extrapolation using the PBPK model of Chiu and Ginsberg (2011) to reduce uncertainties in the OSFs (e.g., see Tetrachloroethylene – IRIS 2014). Even the derivation of Inhalation Unit Risk Factors (URs) have changed, using Multistage models with linear extrapolation from the point of departure (BMCL10), followed by extrapolation to humans using the PBPK model of Chiu and Ginsberg (2011) (e.g., see Tetrachloroethylene – IRIS 2014).

However, even with a reduction of this form of uncertainty in the derivation of OSFs and URs for Human Health Risk Assessments, use of more recent toxicity studies by EPA (and approved by the National Academy of Sciences- NAS) to derive IRIS Toxicity Factors have resulted in values that are more conservative (e.g., see Trichloroethylene – IRIS 2014), such that use of the current IRIS TCE Chronic Inhalation Exposure Reference Concentration (RfC) value of  $2 \mu g/m^3$  (micrograms per cubic meter)<sup>1</sup> for Risk Assessments evaluating short-term Indoor Air Inhalation exposures (Imminent Hazards) to TCE vapors has become problematic, yielding an Hazard Index (HI) = Unity or a value of 1 (one), especially for women in their first eight weeks of pregnancy or involving women of child-bearing age.

In this situation, maybe Risk Assessors should consider Non-Cancer Risk Limits of HI= 2 to 10 to address this site-specific receptor uncertainty.

Another area of uncertainty evolving for Individual and/or Totals Site ELCRs concerns EPA's list of "Emerging Chemical Contaminants" in Drinking Water, where certain chemicals are being added as the result of improvements in Laboratory Analytical Sample Extraction methodology and a consequent drop in a chemical's Laboratory Reporting Limit. An example we have encountered here in MA is 1,4-Dioxane, where the RL has dropped from 200 to 0.02 μg/L (*micrograms per liter*) over time and the chemical is now being detected in municipal water and private drinking water supplies. In addition, the revised IRIS UR for Drinking Water for 1,4-Dioxane addition has dropped 10-fold, resulting in the derivation and drop in a revised MA Office of Drinking Water Guideline (*ORSGL*) Action Level from 3 to 0.3 μg/L for 1,4-Dioxane very close to the RL of 0.02 μg/L and potentially within a Laboratory Reporting Error of up to ±10 % (*percent*). Hence, use of an Individual Cancer Risk Limit of 1 x 10<sup>-5</sup> to address this uncertainty may well be appropriate for CT's consideration.

One minor point, noted both by Risk Management Incorporated (RMI) and the LSPA (*Licensed Site Professionals Association*) Risk Assessors and the board itself, is MassDEP's incorrect calculation of the revised ORSGL value of  $0.3~\mu g/L$ . The correctly calculated and rounded value is  $0.45~\mu g/L$ . MassDEP was notified of this by the LSPA Board and a change requested to the 2014 MCP Revisions in April. However, MassDEP has not recognized the corrected value to date. Hence, this form of Uncertainty should be recognized by states, including CT that adopt rounded rather than raw EPA IRIS UR or RfD Toxicity Values in their derivation of Action Levels etc.!

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<sup>&</sup>lt;sup>1</sup> RfC value of 2 μg/m<sup>3</sup> based on short-term exposure fetal development and immunological system effects (*see TCE – IRIS 2014*)

Depending on the State, the latter should not be an issue, since Site-Specific Risk Assessments such as the MCP Method 3 Risk Characterization used in MA, prohibit the use of Primary MCP Soil and Groundwater Standards for comparison to Chemical Exposure Point Concentrations (EPCs), but allow comparison of MCP-compliant EPCs to other Applicable, Suitable or Analogous Standards, but rendering invalid the use of any secondary MCP/MassDEP derived Action Levels or Guideline Values. Something that should be considered in the event CT DEEP adopts the use of Site-Specific Risk Assessments for Human Health, Ecology, Environment, Public Welfare and Safety.

Thank you for providing us with an opportunity and invitation to submit public comments on the issues and recommendations presented in the subject "Connecticut Risk-Based Decision Making – Final Report dated 29<sup>th</sup> August, 2014."

Sincerely yours,

Risk Management Incorporated Health & Environmental Services

Peter W. Woodman, Ph.D. President, CEO & Co-Founder

Sl/pww